IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC., *et al.*, *Plaintiffs* v. CEPHALON, INC., *et al.*, *Defendants*	No. 2:06-cv-1797
VISTA HEALTHPLAN, INC., *et al.*, *Plaintiffs* v. CEPHALON, INC., *et al.*, *Defendants*	No. 2:06-cv-1833

[PROPOSED] ORDER GRANTING GENERIC DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINTS OF THE DIRECT PURCHASER PLAINTIFFS AND END PAYOR PLAINTIFFS

Upon consideration of Generic Defendants' Motion to Dismiss the Amended Complaints of the Direct Purchaser Plaintiffs and End Payor Plaintiffs, and the oppositions thereto, **IT IS HEREBY ORDERED** that the Motion is **GRANTED** and Plaintiffs' complaints are hereby **DISMISSED**.

Dated: _____, 2009

_____
Honorable Mitchell S. Goldberg
United States District Judge

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GENERIC DEFENDANTS' MOTION TO DISMISS
THE AMENDED COMPLAINTS OF THE DIRECT PURCHASER
PLAINTIFFS AND END PAYOR PLAINTIFFS

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendants Barr Laboratories, Inc., Mylan Inc. (formerly known as Mylan Laboratories, Inc.), Ranbaxy Laboratories, Ltd., Ranbaxy Pharmaceuticals, Inc., Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. (collectively, the "Generic Defendants") move to dismiss the following complaints:

- the First Consolidated Amended Class Action Complaint filed August 10, 2009 by King Drug Company of Florence, Inc., *et al.*, in No. 06-cv-1797;

- the Complaint and Demand for Jury Trial filed August 20, 2009 by Rite Aid Corporation, *et al.*, in No. 06-cv-1797;
- the Amended Consolidated Class Action Complaint of End-Payors filed August 10, 2009 by Vista Healthplan, Inc., *et al.*, in No. 06-cv-1833;
- the Amended Complaint of Avmed, Inc., filed August 10, 2009 in No. 06-cv-1833.

The reasons for granting this Motion are set forth in the accompanying Memorandum in Support.

August 31, 2009

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
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MEMORANDUM IN SUPPORT OF GENERIC DEFENDANTS' MOTION TO DISMISS THE AMENDED COMPLAINTS OF THE DIRECT PURCHASER PLAINTIFFS AND END PAYOR PLAINTIFFS

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INTRODUCTION

This case turns on the basic question whether a defendant to a patent infringement lawsuit is free to enter into a settlement agreement ending the litigation, or if it must—on threat of antitrust treble damages—litigate the case to conclusion. Plaintiffs challenge separate decisions by four generic drug companies—Barr Laboratories, Inc., Teva Pharmaceuticals Industries Ltd./Teva Pharmaceuticals USA, Inc., Ranbaxy Laboratories, Ltd./Ranbaxy Pharmaceuticals, Inc. and Mylan Inc. (formerly known as Mylan Laboratories, Inc.) (collectively "the Generic Defendants")—to settle patent infringement litigation brought under the Hatch-Waxman Act by Cephalon, Inc. concerning the drug Provigil®, the brand name for Cephalon's modafinil product ("Provigil® Settlements"). Rather than continuing with costly and risky patent litigation, the Generic Defendants each made a decision that litigants make every day—they settled. As plaintiffs' complaints make clear, there is nothing extraordinary about these patent settlements, which ended each of the patent litigations and provided certainty for launch before patent expiration. Indeed, the settlements will permit the Generic Defendants to market competing Provigil® products *three years* earlier than they otherwise could have had they continued the litigation and lost.

Notwithstanding this obvious pro-competitive benefit, two groups of plaintiffs—those that purchased Provigil® directly from Cephalon ("Direct Purchasers") and those that purchased Provigil® through an intermediary ("End Payors")—have filed these actions, claiming that the Provigil® Settlements are unlawful restraints on trade in violation of the Sherman Act and state antitrust laws. According to plaintiffs, the Generic Defendants "knew" that the patent asserted by Cephalon as claiming Provigil®

was weak, and they "knew" that they were likely to win the patent litigation. Thus, according to plaintiffs, the Generic Defendants were obligated to continue with the patent litigation, to have the patent declared invalid, to defend that decision on appeal, and to launch a competing generic product. Because the Generic Defendants did not do so, and instead settled their cases, plaintiffs contend that they have engaged in an unlawful market allocation in violation of the antitrust laws.

These claims fail as a matter of law. Every federal appellate court to have considered an antitrust challenge to a Hatch-Waxman litigation settlement has held that, so long as the settlement resolves a bona-fide dispute and does not restrict competition outside the exclusionary zone of the patent, there is no antitrust violation. This makes sense. After all, a patent by definition grants its holder a legal monopoly and the right to exclude competition. There can be no antitrust violation for an agreement that restricts competition only within the patent's scope. Because plaintiffs have not alleged that the Provigil® Settlements restricted competition outside the scope of the patent, plaintiffs cannot state a claim for relief.

The law has long recognized the benefits—to both the parties and the courts—of settlement, and has encouraged settlement, including in patent cases. Plaintiffs' rule would impose antitrust liability for *any* settlement of a patent case based on whether or not a party knew (or should have known) that it had a strong likelihood of success. Such a rule would discourage settlements, increase litigation costs and place greater burdens on the courts. In the Hatch-Waxman context, such a rule would result in *less* competition because generic companies would face greater hurdles in bringing so-called "Paragraph IV" patent challenges and thus would likely challenge fewer drug patents.

Moreover, plaintiffs' claims fail because they have not alleged sufficient facts to state a plausible claim that the Generic Defendants conspired with one another to settle their respective litigations and restrict competition in the Provigil® market. Because plaintiffs allege that, in the absence of a generic conspiracy, the remaining generic companies would have continued, and won, their patent challenges, thereby opening the Provigil® market to competition, the plaintiffs' claims necessarily turn on the existence of such a conspiracy. But the plaintiffs' bald assertion that the Generic Defendants must have conspired with one another to restrict competition is precisely the type of conclusory allegation the Supreme Court has found insufficient as a matter of law to state an antitrust claim.

At the end of the day, there is no basis in law, policy, or logic for a rule that would impose antitrust liability on the defendant in patent litigation for settling that litigation within the scope of the patent. Every court to consider this issue has rejected such antitrust challenges, and there is no reason for this Court to hold otherwise. Because plaintiffs cannot state a claim as a matter of law, the motion to dismiss should be granted, and the complaints should be dismissed.

BACKGROUND

These cases arise out of the settlement of patent litigation between Cephalon and the Generic Defendants, after each of the Generic Defendants sought FDA approval to market a generic version of Cephalon's patented drug Provigil®.

A. The Hatch-Waxman Regulatory Scheme For Approval Of Generic Drugs And Challenges To Brand Manufacturers' Patents

The Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act") amended the Federal Food, Drug and Cosmetic Act and established a

new procedure for obtaining FDA approval to market generic drugs. *See* 21 U.S.C. § 355.[1] The Hatch-Waxman Act is a carefully-drafted statute that balances two conflicting interests: (1) encouraging the development of more affordable generic drugs in a timely fashion, and (2) protecting the patent rights of brand-name drug manufacturers to reward their research and development efforts.

The Hatch-Waxman Act made it easier for generic drug companies to introduce competing versions of a brand-name drug, by allowing the generic company to rely on the FDA's scientific determination that the brand-name drug is safe and effective. To gain approval, the generic company must file what is known as an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). In the ANDA, the applicant must demonstrate that its generic version of the drug is "bioequivalent" to the branded drug, meaning that it works in the same way and provides the same benefits. *See id.* § 355(j)(2)(A)(iv). To protect the patent rights of the branded manufacturer, however, the Hatch-Waxman Act requires the generic challenger to file one of four certifications to any patent the branded company identifies as claiming the product. *See id.* § 355(j)(2)(A)(vii). Of these, two are relevant here: (1) a Paragraph III is a certification that the generic company will not market its product until the patent claiming the brand-name drug expires, *see id.* § 355(j)(2)(A)(vii)(III); and (2) a Paragraph IV is a certification that either the generic drug does not infringe the patent, or that the patent is invalid or unenforceable, *see id.* § 355(j)(2)(A)(vii)(IV). The patents for which certification is required are listed in an FDA publication known as "the Orange Book."

[1] The Federal Food, Drug, and Cosmetic Act has subsequently been amended by the Medicare Modernization Act of 2003 and the Food and Drug Administration Amendments Act of 2007 in ways not pertinent to this case. All statutory references are to the pre-amended version of the statute, unless otherwise noted.

Because a Paragraph IV certification amounts to an assertion by the generic company that the patent on a brand-name drug should not be enforced, the filing of a Paragraph IV certification is a technical act of patent infringement. *See* 35 U.S.C. § 271(e)(1). The filing of a Paragraph IV certification thus allows the brand manufacturer to sue immediately for patent infringement rather than waiting until the generic company introduces its generic drug into the market. Through the resulting litigation, a generic company can obtain a judicial determination regarding patent validity and infringement before taking the risk of producing and selling its potentially-infringing competing product. So long as the generic company waits for the ruling before coming to market, it will be liable for few (if any) damages if it loses the patent case, because it will not have made any infringing sales. On the other hand, the branded manufacturer stands to lose a great deal in the litigation: if the generic company's challenge to the patent is upheld, the generic company can enter the market immediately and the branded manufacturer will lose its patent monopoly forever. *See generally In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 206-07 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1074 (11th Cir. 2005).

As additional protection for brand manufacturers' patent rights, the Hatch-Waxman Act also grants an automatic stay of FDA approval of the proposed generic drug once patent litigation is filed. Thus, if the brand manufacturer brings a lawsuit within 45 days after receiving notice that a generic company has filed a Paragraph IV certification, the FDA cannot grant final approval of the generic drug for thirty months or until the generic manufacturer wins the patent litigation, whichever comes first. *See* 21 U.S.C. § 355(c)(3)(C). If the 30-month stay expires before resolution of the

patent litigation, the generic manufacturer has the option of seeking final FDA approval so that it may immediately launch its generic drug—but at the risk of substantial damages if it loses the patent case. This is known as an "at-risk" launch. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro I*"), 261 F. Supp. 2d 188, 204 (E.D.N.Y. 2003) ("[I]f a generic company that received FDA approval markets its drug before the resolution of the patent infringement suit, the generic company assumes the risk that it may subsequently be found liable for infringement.").

To encourage generic manufacturers to expend the resources necessary to pursue these patent challenges, the Hatch-Waxman Act provides an incentive to the first generic manufacturer to file an ANDA containing a Paragraph IV certification. This "first-filer" receives 180 days of generic marketing exclusivity—meaning that the FDA cannot approve another applicant's ANDA for the same drug product until 180 days after one of two triggering events occurs: either the first commercial marketing of the generic product, or a court decision holding that the patent at issue is invalid or unenforceable. *See* 21 U.S.C. § 355(j)(5)(B)(iv). Eligibility for 180-day generic exclusivity is governed by the Hatch-Waxman Act and FDA regulations, which explain in detail the circumstances in which a generic company may qualify for exclusivity for a particular drug.

B. Factual Background

These cases arise out of decisions by Cephalon and each Generic Defendant to settle their respective patent cases rather than risking a loss in costly winner-take-all litigation. The Generic Defendants strongly contest many of the factual allegations in plaintiffs' complaints, but accept them solely for purposes of the motion to dismiss.

1. Cephalon's Provigil® Drug

Cephalon has FDA approval to market modafinil, a wakefulness-promoting agent used to treat narcolepsy and excessive daytime sleepiness. *See* Directs Compl. ¶¶ 53-54, 63; End Payors Compl. ¶¶ 53-55.[2] Cephalon markets modafinil under the trade-name Provigil®. *See* Directs Compl. ¶ 52; End Payors Compl. ¶ 53. According to plaintiffs, Provigil® sales totaled nearly $850 million in 2008. Directs Compl. ¶ 1; End Payors Compl. ¶ 85. Cephalon lists U.S. Reissue Patent No. 37,516 ("the RE '516 Patent") in the Orange Book as claiming Provigil®. *See* Directs Compl. ¶ 64; End Payors Compl. ¶ 65. According to plaintiffs, the RE '516 Patent is a formulation patent, *i.e.*, it covers a formulation of modafinil using a particular particle size. *See* End Payors Compl. ¶¶ 62, 65. The RE '516 Patent expires in October 2014; however, because Cephalon received the right to an additional six months of exclusive marketing—for having studied the effectiveness of its drug in children (known as "pediatric exclusivity")—its patent-based exclusivity on Provigil® does not expire until April 2015. *See* Directs Compl. ¶¶ 87, 130; End Payors Compl. ¶ 128. Because the RE '516 Patent is listed in the Orange Book, any generic wishing to submit an ANDA for Provigil® is required to file a certification regarding that patent.

Cephalon also received new chemical exclusivity ("NCE") on Provigil®, separate and apart from its patent exclusivity. NCE restricts a generic from even filing an ANDA. In this case, no generic drug company could file an ANDA for Provigil® until

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[2] Citations are to the First Consolidated Class Action Complaint of the Direct Purchasers ("Directs Compl.") and the Amended Consolidated Class Action Complaint of End-Payors ("End Payors Compl."), both of which were filed August 10, 2009. Additional complaints have been filed by Rite-Aid Corporation, on behalf of a separate group of Direct Purchasers ("Rite-Aid Complaint") and Avmed, Inc., a separate End Payor. These complaints, which raise substantively similar allegations, are also covered by this motion to dismiss.

December 24, 2002. Because of yet another exclusivity—"orphan drug exclusivity"—no ANDA for Provigil® could be considered for final approval until, at the earliest, December 24, 2005, regardless of any patents listed in the Orange Book. *See* Directs Compl. ¶¶ 45, 54-57; End Payors Compl. ¶¶ 55-57. On December 24, 2002, all four Generic Defendants (Teva, Barr, Ranbaxy and Mylan) filed individual Provigil® ANDAs, each containing Paragraph IV certifications as to the RE '516 Patent. *See* Directs Compl. ¶ 56; End Payors Compl. ¶ 57. Plaintiffs allege that, because all four Generic Defendants filed their ANDAs on the first possible day, all four were "first filers" and were entitled to share 180 days of marketing exclusivity. *See* Directs Compl. ¶ 56.

2. The Provigil® Patent Litigations

Cephalon filed individual lawsuits against all four companies alleging infringement of the RE '516 Patent, and litigation ensued for two years. *See* Directs Compl. ¶¶ 71, 87; End Payors Compl. ¶¶ 70, 79-80. While motions for summary judgment were pending in late 2005 and early 2006, Cephalon entered into settlement agreements with each of the four Generic Defendants. *See* Directs Compl. ¶¶ 81, 87, 108, 116, 120, 124; End Payors Compl. ¶¶ 80, 82, 101, 112, 117, 120. Each of the settlements resulted in the dismissal of the litigation between Cephalon and the generic company, *see* Directs Compl. ¶ 87; End Payors Compl. ¶ 82, thereby relieving the parties of the costs and risks of further litigation. The complaints allege that each of the settlements also included monetary consideration from Cephalon to the generic company, in exchange for, *inter alia*, rights to intellectual property and product development and supply agreements. *See* Directs Compl. ¶¶ 110, 118-19, 122, 125; End

Payors Compl. ¶¶ 102, 114-15, 118, 121. Significantly, under the Provigil® Settlements, each of the Generic Defendants obtained a license to market a competing product in 2012, *three years earlier* than would otherwise have been permitted under the RE '516 Patent. *See* Directs Compl. ¶ 87; End Payors Compl. ¶ 100.

MOTION TO DISMISS STANDARD

The Supreme Court has recently clarified the showing a plaintiff must make to survive a motion to dismiss under Rule 12(b)(6). The Supreme Court has expressly rejected the "no set of facts" standard set forth in *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957), and replaced it with a standard requiring that the complaint contain factual allegations, which if accepted as true, state a *plausible* claim for relief. *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009); *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 557, 562-63 (2007). It is not enough to plead facts that "permit the court to infer ... the mere *possibility* of misconduct." *Iqbal*, 129 S. Ct. at 1950 (emphasis added). Rather, the complaint's "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555; *see also McTernan v. City of York*, --- F.3d ----, 2009 WL 2581430, at *8-10 (3d Cir. Aug. 24, 2009); *Umland v. Planco Fin. Servs., Inc.*, 542 F.3d 59, 64 (3d Cir. 2008).

Importantly, "[w]here a complaint pleads facts that are 'merely consistent with' a defendant's liability, it 'stops short of the line between possibility and plausibility of entitlement to relief.'" *Iqbal*, 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 557). Moreover, a court need not accept as true plaintiffs' "legal conclusions," "[t]hreadbare recitals of the elements of a cause of action," or "conclusory statements." *Id.* (citing *Twombly*, 550 U.S. at 555). A complaint is not sufficient if it does no more than

"tender[] naked assertions devoid of further factual enhancement." *Id.* (citation and quotation omitted).

ARGUMENT

In their complaints, the Direct Purchaser Plaintiffs and the End Payor Plaintiffs seek to impose antitrust liability on the Generic Defendants because they wish the Generic Defendants had litigated their RE '516 Patent infringement cases to judgment, rather than settling. But there is nothing in the Sherman Act or any state antitrust law that prevents parties in patent litigation from settling that litigation—and thus avoid the costs and risks inherent in all litigation—so long as the settlement does not restrict more competition than would otherwise be excluded by the patent. Indeed, every federal appellate court to have considered a Hatch-Waxman settlement within the scope of the patent has rejected antitrust challenges to the settlement. Because plaintiffs have not alleged that the settlements exceeded the exclusionary zone of the RE '516 Patent, plaintiffs' antitrust claims fail as a matter of law.

Scrutiny of the plaintiffs' complaints is warranted at the motion to dismiss stage. As the Supreme Court recently made clear, "it is only by taking care to require allegations that reach the level suggesting conspiracy that [courts] can hope to avoid the potentially enormous expense of discovery in cases with no 'reasonably founded hope that the discovery process will reveal relevant evidence' to support [an antitrust] claim." *Twombly*, 550 U.S. at 559-60 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005)); *see also Asahi Glass Co. Ltd. v. Pentech Pharms., Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("[T]o avoid turning every patent case into an antitrust case, some threshold of plausibility must be crossed at the

outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase."). Because plaintiffs' claims are deficient as a matter of law, the parties and the Court should not be subjected to a prolonged, expensive, and unnecessary discovery process. The complaints should be dismissed.

I. Hatch-Waxman Settlements That Do Not Exceed The Scope Of The Underlying Patent Do Not Violate The Antitrust Laws.

Even accepting plaintiffs' allegations as true (as required for a motion to dismiss), the Provigil® Settlements did not unreasonably restrain competition. Federal courts have uniformly held that a Hatch-Waxman patent settlement does not violate the antitrust laws unless the settlement restricts competition beyond the exclusionary scope of the patent. Because plaintiffs do not allege that the settlements here restrained competition outside the scope of the RE '516 Patent, plaintiffs' claims under the Sherman Act fail as a matter of law.[3]

A. Every Federal Appellate Court To Have Considered The Issue Has Held That A Hatch-Waxman Settlement Within The Scope Of The Patent Does Not Violate The Antitrust Laws.

The backdrop for plaintiffs' complaints is the settled law that a patent holder is entitled to protect that to which it is legally entitled—a monopoly on the production and sale of the patented good. The U.S. Constitution expressly authorizes Congress "[t]o promote the Progress of Science and useful Arts" by granting inventors "the exclusive Right" to their inventions "for limited Times." U.S. Const. art. I § 8 cl. 8. Congress exercised that authority by enacting the federal patent laws, which expressly

[3] For similar reasons, and for those discussed in Cephalon's motion to dismiss the End Payors' complaint, the End Payors' and Avmed's claims under state antitrust laws should also be dismissed.

grant patent holders "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. 35 U.S.C. § 154(a)(1).

It follows, as a matter of law and logic, that there can be no unlawful restraint of competition for conduct within the scope of a patent. In essence, a patent is a federal license to restrain competition in a particular area for a particular time. *See, e.g.*, *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro Fed. Cir.*"), 544 F.3d 1323, 1337 (Fed. Cir. 2008) (same), *cert denied.* 129 S. Ct. 2828 (2009); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1304 (11th Cir. 2003) ("A patent grants its owner the lawful right to exclude others."); *W. L. Gore & Assocs., Inc. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976) ("The right to refuse to license is the essence of the patent holder's right under the patent law which rewards invention disclosure by the grant of a limited monopoly in the exploitation of the invention."). By definition, then, there can be no unlawful restraint of competition within the zone of patent exclusivity. *See, e.g.*, *United States v. General Elec. Co.*, 272 U.S. 476, 485 (1926); *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992); *United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1128 (D.C. Cir. 1981); *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981); *United States v. CIBA GEIGY Corp.*, 508 F. Supp. 1118, 1150 (D.N.J. 1976).[4]

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[4] Plaintiffs cannot avoid this straightforward point by arguing that "Cepalon's patent did not give it an automatic right to exclude its generic competitors, but rather a right to try to use its patent to obtain a court order excluding or enjoining generic competition." Directs Compl. ¶ 93; End Payors Compl. ¶ 88. As an initial matter, this is wrong as a matter of law. *See, e.g.*, *Cipro Fed. Cir.*, 544 F.3d at 1337 ("[P]atent law bestows the patent holder with 'the right to exclude others from profiting by the patented invention.'" (quoting *Dawson*, 448 U.S. at 215)). And, in any event, plaintiffs' argument

For this reason, federal courts have uniformly held that an agreement to settle Hatch-Waxman patent litigation does not—as a matter of law—give rise to antitrust liability so long as the settlement agreement is limited to the patent's exclusionary zone. *See Cipro Fed. Cir.*, 544 F.3d at 1336 ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."), *aff'g In re Ciprofloxacin Hydrochloride Antitrust Litig.* ("*Cipro II*"), 363 F. Supp. 2d 514, 523 (E.D.N.Y. 2005) ("The ultimate question ... [is] whether any adverse effects on competition stemming from the [settlement] were outside the exclusionary zone of the [patent]."); *Tamoxifen*, 466 F.3d at 213 ("[T]he question is whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'" (quoting *Schering-Plough*, 402 F.3d at 1076)); *Valley Drug*, 344 F.3d at 1311 (focusing on the "exclusionary potential of the patent"); *see also Asahi Glass*, 289 F. Supp. 2d at 992-93 (similar); *In re K-Dur Antitrust Litig.*, No. 01-1652-JAG, 2009 WL 508869, at *27 (D.N.J. Feb. 6, 2009) (similar); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. JCCP-4154 (Cal. Super. Ct. Aug. 21, 2009) (granting summary judgment) (Attach. A).

That approach fully and properly reconciles the federal patent laws with the federal antitrust laws. After all, "a patent by its very nature is anticompetitive," *Cipro Fed. Cir.*, 544 F.3d at 1333, meaning that "[w]hatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly," *Tamoxifen*,

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does not make sense. Under plaintiffs' view of the world, one does not have an "automatic right" to petition the government, or be represented by an attorney in a criminal trial, or to own private property, but rather a right to file civil litigation seeking to enforce that right. But it is the right itself that gives rise to the litigation claim in the first place. Plaintiffs' circular reasoning does not change the fact that a patent, by its very nature, permissibly excludes competition.

466 F.3d at 212-13. As the Federal Circuit has explained: "A settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention." *Cipro Fed. Cir.*, 544 F.3d at 1337. If the settlement agreement does no more than to confirm a bar on conduct that the patent itself prohibits, there is no antitrust violation as a matter of law. On the other hand, "exposing settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent ... would undermine the patent incentives" by negating the lawful monopoly that lies at the heart of the patent laws. *Valley Drug*, 344 F.3d at 1308.

Tamoxifen is particularly instructive. In *Tamoxifen*, the Second Circuit affirmed an order of the district court dismissing pursuant to Rule 12(b)(6) an antitrust challenge to a Hatch-Waxman patent settlement. 466 F.3d at 216. In that case, the patent holder settled with the generic challenger *after* the patent had been declared invalid by the district court and while the case was on appeal. *Id.* at 205. Nonetheless, the Second Circuit held that the appropriate standard in the antitrust analysis was whether the terms of the settlement agreement exceeded the scope of the patent at issue. *Id.* at 213. Because plaintiffs did not allege the settlement exceeded the exclusionary potential of the patent, their claims failed as a matter of law. *Id.* at 218 ("[B]ecause [the settlement] did not exceed the scope of the tamoxifen patent, it was not an *unlawful* anticompetitive agreement."); *see also Asahi Glass*, 289 F. Supp. 2d at 992-93 (granting a 12(b)(6) motion to dismiss an antitrust challenge to a Hatch-Waxman settlement because "the patent *may well* be valid" and the patentee "cannot be faulted to trying to enforce it" (emphasis in original)).

Plaintiffs cannot credibly argue that the federal courts are divided on this issue. As the language quoted above makes clear, the Second, Eleventh and Federal Circuits, as well as Judge Posner and Special Master Orlofsky in the District of New Jersey have all used the same legal standard to evaluate settlements of Hatch-Waxman litigation. *See Cipro Fed. Cir.*, 544 F.3d at 1334-36 (rejecting the argument that the standards adopted by the various federal courts are in conflict). Indeed, the U.S. Supreme Court recently denied a petition for certiorari filed by the plaintiffs in the Federal Circuit *Cipro* case that argued the federal decisions are in conflict. *See* 129 S. Ct. 2828.

The Sixth Circuit's holding in *In re Cardizem CD Antitrust Litigation* does not alter this analysis. *See* 332 F.3d 896, 908 (6th Cir. 2003) (holding that an interim agreement between a brand and generic company arising in the context of a Hatch-Waxman patent case violated the antitrust laws); *see also Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001) (addressing the same interim agreement). Indeed, the Federal Circuit specifically distinguished *Cardizem*, noting that the agreement at issue included a provision preventing the generic company from marketing drugs not covered by the relevant patent and thus "clearly had anticompetitive effects outside the exclusion zone of the patent." *Cipro Fed. Cir.*, 544 F.3d at 1335; *see also Tamoxifen*, 466 F.3d at 213-14 (distinguishing *Cardizem* on the same ground). This distinction was also noted by the Solicitor General's office in its brief recommending that certiorari be denied in *Tamoxifen*. *See* Br. for the United States as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830, 2007 WL 1511527, at *16 n.7 (U.S. May 23, 2007) ("*Cardizem* involved payments to exclude competition in

drugs that did *not* fall within the scope of the allegedly infringed patent, and it is thus uncertain whether the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case." (emphasis in original)). Moreover, the agreement at issue in *Cardizem* was not a "settlement" at all; rather, it involved a mere "interim" agreement that did not end the patent litigation. 332 F.3d at 902-03.

The standard established by federal courts to evaluate Hatch-Waxman settlements is not new law; to the contrary, it is derived from the long-standing rule, established by the Supreme Court and applied by the Third Circuit, that the relevant question in an antitrust challenge concerning a patent is whether the conduct at issue *exceeds* the exclusionary zone of the patent. *See, e.g.*, *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964) ("[A patent] cannot be used to secure any monopoly beyond that contained in the patent." (internal citation omitted)); *United States v. Singer Mfg. Co.*, 374 U.S. 174, 197 (1963) ("[T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."*)*; *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) ("A patent affords no immunity for a monopoly not fairly or plainly within the grant."); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 519 (1917) (similar).

When the Supreme Court has permitted a finding of antitrust liability in a case involving a patent, it has specifically noted that the defendant's conduct exceeded the exclusionary rights granted by the patent. For instance, in *Motion Picture Patents*, the Court held that a license granted by the patentee on a movie projector violated the antitrust laws because it contained an ancillary restriction on the type of film that

could be used in the machines, which was not covered by any patent. 243 U.S. at 518-19. Likewise, in *Masonite*, the Court found an antitrust violation in the patentee's attempts to set prices throughout the entire supply chain, not just at the first sale, because this exceeded the scope of the rights granted by the patent. 316 U.S. at 277-78. Finally, in *Singer*, the Court found that three sewing machine manufacturers, Singer, Gegauf and Vigorelli, conspired and acted in concert to suppress competition from Japanese manufacturers. 374 U.S. at 194. In so holding, the Court focused on an "entire course of dealings between the parties," *id.* at 190 n.7, where "by entwining itself with Gegauf and Vigorelli in such a program Singer went far *beyond* its claimed purpose of merely protecting its own 401 machine" over which it had a patent, *id.* at 194 (emphasis added). Cases like this are clearly distinguishable from this case.

The Third Circuit—in cases decided before jurisdiction over patent appeals was transferred to the Federal Circuit—adopted the same approach: conduct within the scope of a patent could not give rise to a claim for antitrust violations or patent misuse. *See, e.g.*, *W. L. Gore*, 529 F.2d at 624 (recognizing that "an attempt to extend a patent monopoly *beyond the patent claims or the limited period of the monopoly grant* necessarily runs counter to the patent laws" (emphasis added)); *Baldwin-Lima-Hamilton Corp. v. Tatnall Measuring Sys. Co.*, 268 F.2d 395, 396 (3d Cir. 1959) (affirming a holding of patent misuse because the patentee's actions "constituted an illegal expansion of the monopoly conferred by the [] patent ... beyond that contemplated by the patent grant"); *National Lockwasher Co. v. George K. Garrett Co.*, 137 F.2d 255, 256 (3d Cir. 1943) (holding that the patentee could not "extend the bounds of its lawful monopoly" through "use of the patent to purge the market of

competing non-patented goods" and finding liability only "to the extent that the patentee is using the lawful monopoly granted by the patent as a means of suppressing the manufacture and sale of competing *unpatented* articles" (emphasis added)). District courts within the Third Circuit continue to adhere to this well-established rule of law. *See, e.g.*, *Sheet Metal Duct, Inc. v. Lindab, Inc.*, No. 99-6299, 2000 WL 987865, at *2-3 (E.D. Pa. July 18, 2000) ("[A]ny allegation of antitrust resulting from a patent must extend beyond the rights granted in the patent ...." (citations omitted)); *CIBA GEIGY*, 508 F. Supp. at 1150 ("[W]here a patentee exercises his patent in an effort to expand his monopoly beyond that reasonably implicit in the patent grant, he may collide with the antitrust laws." (citing *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20, 48 (1912))).

The rule set forth by federal courts is thus clear and perfectly in line with settled patent and antitrust law. So long as the settlement entered into by the parties does not exceed the patent's exclusionary scope, any restraint on competition occurs as a result of the patent, not the agreement, and there can be no antitrust liability.

B. Plaintiffs Have Not Alleged That The Provigil® Settlements Exceeded The Scope Of The Patent.

The complaints of both the Direct Purchasers and the End Payors fail to state a claim as a matter of law because neither makes *any* allegation regarding the scope of the RE '516 Patent, much less the required showing that the settlement agreements exceeded that scope. Indeed, the complaints all but ignore the exclusionary effect of the patent, despite the fact that it is vital to the legal question presented by this case. Perhaps cognizant of the prevailing legal standard, however, plaintiffs' complaints

contain two categories of allegations that attempt to satisfy the requirement of an "outside the scope" allegation. Neither withstands scrutiny.

First, the complaints raise allegations concerning the operation of the Generic Defendants' 180-day generic exclusivity period, which they obtained by being the first filers of an ANDA containing a Paragraph IV certification. Specifically, plaintiffs allege that by holding on to the 180-day generic exclusivity period that they lawfully received from FDA, the Generic Defendants wrongfully delayed competition by other generic manufacturers. Such allegations are wholly unavailing. Importantly, plaintiffs' various statements regarding the 180-day exclusivity period, *see* Directs Compl. ¶¶ 134-37; End Payors Compl. ¶¶ 128-31, are *not* allegations that the Provigil® Settlements extend beyond the scope of the patent. Nor do plaintiffs allege that any Generic Defendant agreed not to relinquish its statutory exclusivity. Instead, plaintiffs merely allege that because "the Generic Defendants have refrained from launching their generics," they have "prevent[ed] their shared 180-day exclusivity period from running," thereby creating a "bottleneck" that has prevented other competitors, including Apotex, from being able to market competing Provigil® products. *See* Directs Compl. ¶¶ 134, 136; *see also* End Payors Compl. ¶¶ 128-31.

But plaintiffs' real complaint is not with the Generic Defendants at all, but rather with the operation of the Hatch-Waxman Act itself. Such allegations are not cognizable. *See, e.g.*, *City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 266 (3d Cir. 1998); *CBC Cos. v. Equifax, Inc.*, 561 F.3d 569, 573 (6th Cir. 2009) ("No cognizable antitrust injury exists where the alleged injury is a 'byproduct of the regulatory scheme' or federal law rather than of the defendant's business practices."). The 180-

day generic exclusivity period is a product of the Hatch-Waxman Act and the FDA's interpretative regulations. It is the statute, and not the Provigil® Settlements, that creates the 180-day exclusivity period and specifies that it does not begin to run until either (1) a final judgment declaring the patent invalid, or (2) the marketing of the generic product by the first-filer(s). *See* 21 U.S.C. § 355(j)(5)(B)(iv). Indeed, Congress has since amended the statute to provide that exclusivity could be forfeited for failing to market a generic drug in certain circumstances, *see* 21 U.S.C. § 355(j)(5)(D)(i)(I) (2009), but that was not the law in effect at the time of the Provigil® Settlements. Congress's change in the law certainly does not give rise to an antitrust claim—if anything it confirms that based on the law in effect at the time, each Generic Defendant had a statutory right to maintain its claim to 180-day exclusivity. Plaintiffs can point to no authority requiring a generic company to relinquish this statutory right when settling patent litigation, because there is none.

Nor is the failure of any Generic Defendant to voluntarily relinquish its right to generic exclusivity evidence of any agreement with Cephalon to restrain competition. *See Iqbal*, 129 S. Ct. at 1949-50. To the contrary, such conduct "is easily explained by [their] own interest in protecting [themselves] from competition through … a statutorily prescribed benefit." *Tamoxifen*, 466 F.3d at 218. Any suggestion that the Generic Defendants "manipulated" anything merely by following the law is therefore a red herring. *See, e.g.*, End Payors Compl. ¶ 34 ("Defendants used the Hatch-Waxman Amendments to unlawfully prevent generic entry into the market ...."). It is not possible for private parties to change the existence of a statutory right.

Moreover, it is ironic that the Direct Purchasers and End Payors point to Apotex as having been "prevent[ed] ... from launching its generic [product]." Directs Compl. ¶ 135. After all, it is Apotex that has allegedly been in a position all along to trigger the Generic Defendants' exclusivity and open the floodgates to competing Provigil® products. Apotex did not file an ANDA on Provigil® until more than *two years* after the Generic Defendants. This delay was not caused by the Provigil® Settlements, which were entered into after Apotex filed its ANDA. And when Apotex did get around to filing an ANDA, it did not even challenge the RE '516 Patent with a Paragraph IV certification. Instead, Apotex filed a Paragraph III certification, effectively conceding the validity of the patent, and declaring that it would not introduce its generic Provigil® product until *after* the RE '516 Patent had expired. Only after the Provigil® Settlements were executed did Apotex amend its ANDA, changing its Paragraph III certification to a Paragraph IV certification and asserting (for the first time) that the RE '516 Patent was invalid or not infringed. At the same time, Apotex commenced its lawsuit, raising an antitrust claim in addition to its claim for a declaratory judgment that the RE '516 patent was invalid or not infringed. As Apotex's lawsuit proves, Apotex (like other generic drug companies) has been able all along to challenge the RE '516 Patent, trigger the Generic Defendants' 180 days of exclusivity, and attempt to get their products on the market. That is exactly what the Hatch-Waxman Act contemplates. *See, e.g.*, *Teva Pharms., USA, Inc. v. FDA*, 182 F.3d 1003, 1007-08 (D.C. Cir. 1999); *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1073-74 (D.C. Cir. 1998). The Generic Defendants have done nothing to impede this process.

Second, the End Payors' complaint and the Rite-Aid complaint (but not the Direct Purchasers' complaint) also allege that the Provigil® Settlements precluded the Generic Defendants from marketing products not at issue in the underlying patent litigation. *See* End Payors Compl. ¶ 132 ("The settlement agreements prevented [the Generic Defendants] from selling generic Provigil at issue in the patent litigation, as well as developing and marketing any other generic versions of Provigil."); *id.* ¶ 133 ("[U]nder their agreements with Cephalon, the Generic Defendants may not sell generic products whether or not they infringe Cephalon's Particle Size Patent. Cephalon's patent lawsuit, in contrast, had the potential to restrict only sales of these companies' current versions of generic Provigil, the products at issue in the litigation."); *see also* Rite-Aid Compl. ¶¶ 52, 96, 104, 108. But these allegations, which are accepted only for the purposes of this motion, are insufficient to state an antitrust claim.

As an initial matter, the patent litigation plainly had the potential to limit the eventual ability of each of the Generic Defendants to sell not only the particular modafinil formulation in its ANDA but also any generic Provigil® product covered by Cephalon's proposed construction of the RE '516 patent claims. Indeed, Cephalon's proposed construction in the Provigil® litigation was broader than any one Generic Defendant's product, reaching not only all four proposed formulations, but all generic versions of Provigil®. Cephalon asserted that any formulation of modafinil that had the pharmacological benefits of Provigil® (*i.e.*, any generic drug that would be AB-rated to Provigil®) necessarily infringed the RE '516 Patent.[5] Tellingly, plaintiffs do not challenge the *bona fides* of Cephalon's claim construction.

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5 *See* Cephalon's Motion to Dismiss the FTC's First Amended Complaint at § II.A (pp.41-43).

In any event, allegations regarding the scope of the litigation are *not* analogous to allegations that the settlements exceeded the scope of *the RE '516 Patent itself*. The determination of the "scope" of a patent is a far different inquiry than whether one particular product infringes that patent, or even whether a patent is valid. *See Tamoxifen*, 466 F.3d at 209 n.22 (noting that a settlement can be within the scope of the patent even if the patent is declared invalid). As the cases have made clear, the "scope" of the patent is the definition of the patent's "exclusionary potential." *Schering-Plough*, 402 F.3d at 1066. This "exclusionary potential" includes all possible products that would infringe the patent as issued, not just the particular products at issue in a patent trial. *See Dawson Chem.*, 448 U.S. at 215 ("The essence of a patent grant is the right to exclude others from profiting by the patented invention."); *see also supra* n.5.

The patent litigations in this case concerned only four products—the generic versions of Provigil® developed by each of the Generic Defendants. But that does not mean that those are the *only* products that could potentially infringe the RE '516 Patent, and thus fall within the scope of that patent. Indeed, parties entering into settlement agreements, as the defendants did here, are well within their rights to include additional products within those agreements so long as those products are tethered to the patent at issue. For this reason, to the extent that patent settlement agreements, such as those at issue here, are alleged merely to include more than the specific products directly at issue in the patent cases, such allegations are insufficient to establish an antitrust violation as a matter of law. All that matters is whether there is an allegation that any product was beyond the scope of the patent. The plaintiffs have not made that allegation in this case, and this failure dooms Plaintiffs' claims.

Moreover, to the extent plaintiffs' allegations could be read as claiming the Provigil® Settlements exceeded the scope of the RE '516 Patent (which they cannot), those allegations cannot withstand scrutiny under *Twombly* and *Iqbal*. As the Supreme Court made clear in those cases, conclusory statements without a factual predicate are insufficient to defeat a 12(b)(6) motion. *Iqbal*, 129 S. Ct. at 1949. After all, Fed. R. Civ. P. 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 1950; *see also Twombly*, 550 U.S. at 555. That is precisely the case here. Plaintiffs identify no products that the Generic Defendants have pulled off the shelves or refrained from selling since the date of the Provigil® Settlements. It is not sufficient for plaintiffs to refer generally to "generic equivalents of successor products," *see, e.g.*, End Payors Compl. ¶ 132, without alleging what those products are, whether such products could even exist, or that such products would not be covered by the RE '516 Patent. Vague, conclusory references to hypothetical future products that would need FDA approval to be marketed at all are insufficient to create a cognizable claim of harm to competition. *See, e.g.*, *Ranke v. Sanofi-Synthelabo Inc.*, 436 F.3d 197, 204 (3d Cir. 2006) (affirming an order granting a motion to dismiss because plaintiffs were not entitled to "a fishing expedition in order to find a cause of action"); *McCloskey v. Mueller*, 446 F.3d 262, 271 (1st Cir. 2006) (same). Because plaintiffs' complaints do no more than "tender[] naked assertions devoid of further factual enhancement," *Iqbal*, 129 S. Ct. at 1949 (citation and quotation omitted), they fail to state a claim.

II. Hatch-Waxman Settlements Within The Scope Of The Patent Do Not Become Unlawful Based On Allegations That The Patent Is "Weak" Or That The Generic Defendants Would Have Won The Prior Litigation.

Plaintiffs' other allegations likewise are insufficient to state a valid antitrust claim. Plaintiffs cannot state a claim based on allegations that the underlying patent claims were "weak" or that it was "highly likely" that the Generic Defendants would have won the underlying litigation. Plaintiffs have not alleged that the underlying litigation was a sham, and even if they had, this would not change the antitrust analysis for the claims against the Generic Defendants. And plaintiffs' allegations are based on nothing more than speculation about what the outcome of litigation would have been, which is fatally speculative under federal law.

A. Plaintiffs' Allegations That The Underlying Patent Claims Were "Weak" Are Legally Irrelevant.

Plaintiffs' complaints reduce to an allegation that the Generic Defendants should not have settled the litigations over the RE '516 Patent. According to plaintiffs, Defendants "knew (or should have known)" that Cephalon's patent claims were "*weak*," and the Generic Defendants' patent defenses were "*strong*." Directs Compl. ¶ 88 (emphasis added); End Payors Compl. ¶ 83 (similar); *see also* Directs Compl. ¶ 6 ("Cephalon knew that its patent and its patent infringement claims were weak"); *id.* ¶ 93 (similar); End Payors Compl. ¶ 5 (similar); *id.* ¶ 88 (similar). For this reason, plaintiffs contend, the Generic Defendants' decision to settle the litigation, rather than continue to challenge the patent and seek to introduce a competing Provigil® product, violated the antitrust laws. However, nothing less than an allegation that the patent litigation was objectively baseless is sufficient to support an antitrust claim. Absent a sham, plaintiffs cannot prevail. *See, e.g.*, *Tamoxifen*, 466 F.3d at 208-09 ("[S]o long as

the patent litigation is neither a sham nor objectively baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."); *Asahi Glass*, 289 F. Supp. 2d at 995 ("[A]n infringement suit must be adjudged to be objectively baseless before it can be considered an unlawful method of competition ...."); *K-Dur*, 2009 WL 508869, at *27. Plaintiffs have not alleged that the patent litigation was an objectively baseless sham—and, as such, allegations about the "weakness" or "strength" of the patent case are entirely beside the point.

As an initial matter, it is unclear whether even a finding of sham litigation could amount to an antitrust violation against the Generic Defendants, who were, after all, the *defendants* in the underlying patent litigation. It was not their decision to bring the litigation, making any determination about whether such litigation was objectively baseless irrelevant in determining whether the Generic Defendants violated the antitrust laws. Plaintiffs make no argument (nor could they) as to why a defendant faced with the risks and costs of litigation should ever be precluded from ending that litigation, including through settlement, regardless of the merits of the case or the reason the case was brought. After all, "[n]o one can be *certain* that he will prevail in a patent suit." *Asahi Glass*, 289 F. Supp. 2d at 993 (emphasis in original).

In any event, plaintiffs have not alleged that the underlying litigation was objectively baseless. Allegations that a case is "weak" or that it is "highly likely" that a party would have lost on the merits is *not* the same as an allegation that litigation was "objectively baseless." For the underlying litigation to meet this standard, it must be "objectively baseless in the sense that no reasonable litigant could realistically expect

success on the merits." *Prof'l Real Estate Investors, Inc v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 60 (1993). Litigation is not objectively baseless, however if "an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome ...." *Id.*; *see also Cherninor Drugs, Ltd v. Ethyl Corp.*, 993 F. Supp. 271, 281 (D.N.J. 1998) (case must be shown to have "absolutely no objective merit"), *aff'd*, 168 F.3d 119 (3d Cir. 1999); *K-Dur*, 2009 WL 508869, at *28.

Allegations about what the Defendants "knew" establish only *subjective* knowledge, and thus are irrelevant to the *objectively* baseless determination. As Judge Posner explained, allegations that the defendants "knew when they settled [patent litigation] that [the generic's] product would not infringe [the] patent" are insufficient because "the private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case." *Asahi Glass*, 289 F. Supp. 2d at 992 (granting motion to dismiss). "[I]f a patent infringement suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial." *Id.* at 993; *see also PRE*, 508 U.S. at 60 (holding that "only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation"). Because plaintiffs have, at most, alleged that Defendants had subjective knowledge, not that no reasonable litigant could realistically expect success on the merits, plaintiffs have not pleaded an allegation that the underlying patent litigation was objectively baseless.

Moreover, there is no basis in law or logic for restricting the ability of a defendant in a patent infringement case to settle the litigation based on the defendant's alleged assessment of the strength or weakness of its patent case. It is

precisely because litigation is uncertain—notwithstanding any Monday-morning quarterbacking by the antitrust plaintiffs—that courts uniformly have held that it is vital that generic companies bringing Hatch-Waxman challenges have the full range of litigation options, including settlement, available to them. Put simply, "there is no legal basis for restricting the right of a patentee to choose its preferred means of enforcement and no support for the notion that the Hatch-Waxman Act was intended to thwart settlements." *Cipro Fed. Cir.*, 544 F.3d at 1337.

A generic company's incentive to file an ANDA containing a Paragraph IV challenge to a patent in the first place depends in significant measure upon having the flexibility to decide when, and on what terms, to resolve the litigation rather than fighting "to the death" in every case. *See Valley Drug Co.*, 344 F.3d at 1299, 1308; *Asahi Glass*, 289 F. Supp. 2d at 994. As Judge Trager recognized in upholding the Cipro Settlement:

> The incentives created by the Hatch-Waxman Amendments have led to generic investment in product development, patent review and product challenges through litigation. Indeed, Barr has admitted that it has over ten ANDA challenges in litigation today and more than twice that number under review. To maximize these incentives, a generic company should be permitted to choose not only when to commence patent litigation, but also when to terminate it. Otherwise, the incentives to mount an ANDA IV challenge could be reduced.

Cipro I, 261 F. Supp. 2d at 256 (citations omitted).

Indeed, in affirming Judge Trager, the Federal Circuit explicitly rejected an argument similar to plaintiffs' argument here. *See Cipro Fed. Cir.*, 544 F.3d at 1333-34. The *Cipro* plaintiffs contended that an agreement not to challenge a patent violated the antitrust laws because there is a "vital public interest" in patent

challenges and a patent may very well be shown to be invalid or not infringed in litigation. *Id.* But, the court held, this argument is meritless because "[s]ettlements in patent cases ... frequently provide that the alleged infringer will not challenge the validity of the patent." *Id.* "Thus, the mere fact that the Agreements insulated [the patent holder] from patent validity challenges by the generic defendants was not in itself an antitrust violation." *Id.*

Assessing antitrust liability merely because a generic company settled a claim on which it was possible, or even likely, to prevail, would increase the costs of patent challenges and add additional burdens to raising such challenges. This, in turn, would reduce patent challenges and decrease competition, and thus itself would be anticompetitive. This Court should decline to adopt such a rule.

B. Plaintiffs Cannot State A Claim For An Antitrust Violation Based On Speculation Regarding What Might Have Happened Differently In Prior Litigation.

For much the same reasons, plaintiffs' allegations that "it was *highly likely* that Cephalon would have lost on the merits in all of the patent litigation involving Provigil," Directs Compl. ¶ 88 (emphasis added); End Payors Compl. ¶ 83 (similar), or that the Generic Defendants could have settled on better terms, *see* End Payors Compl. ¶¶ 96-97; Directs Compl. ¶ 129, are also unavailing. Such raw speculation about the outcome of prior judicial proceedings cannot support a cause of action under the antitrust laws.[6] Plaintiffs' claims fail for at least two reasons.

[6] The speculative nature of plaintiffs' allegations also deprives them of standing to bring their claims, as set forth in Cephalon's memoranda in support of its motions to dismiss the complaints of the Direct Purchasers/Rite-Aid (§ V) and the End Payors/Avmed (§ II).

First, antitrust liability cannot be premised on plaintiffs' speculation about what the outcome of the patent litigation would have been. The central feature of plaintiffs' claim is that, absent the Provigil® Settlements, "the Generic Defendants likely would have prevailed in the patent suits." Directs Compl. ¶ 7; *see also, e.g.*, *id.* ¶ 88 (describing it as "highly likely" that Cephalon "would have lost on the merits"); End Payors Compl. ¶ 88 (same). Yet, had the Generic Defendants lost the patent litigation, plaintiffs would wish the Generic Defendants had settled so as to ensure generic competition three years earlier than otherwise permitted under the patent. It is precisely because the outcome of litigation is uncertain that the Supreme Court and other courts have made clear that "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 157, 159-60 (1990) (discussing the potential success of a criminal appeal); *see also City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 267 (3d Cir. 1998) (rejecting plaintiffs' attempt to base antitrust claim on probable outcome of administrative proceeding because plaintiffs "cannot foist their version of what might have been on the court").

For this reason, federal courts addressing the antitrust implications of Hatch-Waxman settlements have universally declined to engage in such speculative analysis. As the Eleventh Circuit has stated: "Patent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages...." *Valley Drug*, 344 F.3d at 1308. Because "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into," *id.* at 1306, any guess as to how

the patent litigation would have turned out is "of limited value in assessing the behavior of the defendants at the relevant time: when they were entering into the Settlement Agreement." *Tamoxifen*, 466 F.3d at 204; *see also Cipro Fed. Cir.*, 544 F.3d at 1337 (same). Moreover, "making the legality of the patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether." *Cipro II*, 363 F. Supp. 2d at 529. Thus, speculation on what might have occurred cannot support a claim of antitrust liability.[7]

Plaintiffs attempt to evade this straightforward point by alleging that the Generic Defendants would have launched "at risk," regardless of whether the patent litigation had concluded. *See, e.g.*, Directs Compl. ¶ 92 (alleging that "Generic Defendants would come to market" soon after December 2005 "regardless of the patent litigation"); *id.* ¶ 100 ("The Generic Defendants also expected to enter the market, even if that meant launching their generic products 'at risk,' that is, while Cephalon's patent suits were still pending."); End Payors Compl. ¶ 134 (alleging that, but for the Provigil® Settlements, "each and all of the Generic Defendants ... would have commenced selling their less expensive generic versions of Provigil by no later than January 2006"); *see also, e.g.*, Directs Compl. ¶¶ 7-8, 58, 128; End Payors Compl. ¶¶ 6, 87, 90, 147.

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[7] Indeed, it would make no difference to the antitrust inquiry even if this Court were to subsequently hold that the patent is invalid. *See, e.g.*, *Valley Drug*, 344 F.3d at 1308 (holding that it was not legally proper to "expos[e] settling parties to antitrust liability for the exclusionary effects of a settlement reasonably within the scope of the patent merely because the patent is subsequently declared invalid"); *Tamoxifen*, 466 F.3d at 210 (affirming an order granting a motion to dismiss under Rule 12(b)(6) challenging the settlement of Hatch-Waxman litigation *after* the patent was held *invalid* by the district court and while the case was on appeal). As *Tamoxifen* and *Valley Drug* illustrate, it does not matter whether a final judgment of invalidity or noninfringement *might* subsequently issue (or even be likely). Because litigation is inherently uncertain, parties are entitled to settle their claims without the specter of antitrust liability.

But this is no different than alleging either that the Generic Defendants "would have won" the patent litigation or that they believed they would win. After all, even though the Hatch-Waxman Act permits a generic manufacturer to launch its generic product prior to the end of the patent litigation, the ultimate success of such a launch is subject to the generic company winning the patent case. If the generic company launches at risk and subsequently loses the litigation, its "competition" is declared illegal and must cease immediately. In that situation, the generic must not only pull its infringing product off of the market, but also could be liable for significant monetary damages.

Like the "would have won" claims, then, plaintiffs' "what if" allegations regarding a possible launch at risk do not establish a cognizable antitrust claim. It simply makes no difference whether one or more of the Generic Defendants *might* have launched its generic product prior to the conclusion of the patent litigation, notwithstanding the significant risks. Any such allegation suggests nothing more than that the defendant believed it would ultimately prevail in the patent litigation, which is insufficient to support an antitrust claim.

Second, an argument that the Generic Defendants should have taken action that was arguably *more* "pro-competitive," either by continuing the patent litigation or entering a settlement with arguably "more" favorable terms for consumers, is not sufficient to state an antitrust claim. *See, e.g.*, Directs Compl. ¶ 129. As an initial matter, plaintiffs' theory ignores the possibility that failure to settle could have resulted in the Generic Defendants *losing* the patent litigation, thereby assuring no generic entry until the patent expired. And, in any event, the Supreme Court has

made clear that the antitrust laws do not require "that a monopolist alter its way of doing business whenever some other approach might yield greater competition." *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 415-16 (2004). The legally relevant inquiry thus is not whether plaintiffs can imagine a hypothetical alternative settlement under which they contend consumers would have been "better off," but whether the settlement that was reached constituted an *unreasonable* restraint of trade. As detailed above, the answer to this question is no. *See Cipro II*, 363 F. Supp. 2d at 536 (holding that a brand manufacturer and generic company "cannot be penalized just because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the [patent]").

A holding to the contrary would have staggering consequences for all litigation settlements. Plaintiffs' proposed rule would expose to antitrust liability not just every Hatch-Waxman settlement, but virtually *every* settlement in patent, antitrust, or intellectual property cases, because a plaintiff purporting to represent consumers could always file suit after the fact and allege either that the parties should not have settled the litigation, or that the parties should have reached some other deal that arguably would have been more pro-competitive. In the specific context of Hatch-Waxman litigation, such a rule would deprive consumers of settlements, like the ones in this case, that allow generic challengers to sell a lower-priced competing product sooner than the patent otherwise would have permitted. And, as discussed above, it could lead to fewer patent challenges by generic companies in the first place.

III. This Court Should Reject The Argument That Hatch-Waxman Settlements Containing Monetary Payments Are Presumptively Unlawful Or *Per Se* Illegal.

Plaintiffs' complaints thus fail as matter of law under the prevailing legal standard, and there is no reason for this Court to adopt a different legal test for evaluating Hatch-Waxman patent settlements. In particular, the Court should reject—as have all courts to consider settlements within the scope of the patent—arguments that a Hatch-Waxman settlement is "presumptively unlawful" or *per se* illegal merely because it allegedly involves the flow of monetary consideration to a generic challenger.

A. Hatch-Waxman Settlements Involving Monetary Payments Are Not Presumptively Unlawful.

Recently, in response to an invitation by the Second Circuit, the government proposed a legal standard whereby a Hatch-Waxman settlement containing monetary consideration paid from the patent holder to the generic challenger would be "presumptively unlawful." *See* Br. for the United States in Response to the Court's Invitation, *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, No. 05-2851-cv, 2009 WL 2429249, at 22-23 & n.7 (2d Cir. July 6, 2009) ("U.S. 2d Cir. Br."). According to the government, such a payment is suspect because it "is naturally viewed as consideration for the generic's agreement to delay entry beyond the point that would otherwise reflect the parties' shared view of the likelihood that the patentee would ultimately prevail in the litigation." *Id.* at 22. The government would thus place the burden on the antitrust defendants to prove that the settlement was *not* anti-competitive. *Id.* at 27-28. This proposed standard parrots the legal test that was rejected by the Eleventh Circuit in *Schering-Plough*. *See* 402 F.3d at 1075-76. It has never been adopted by any court, and this Court should not be the first to adopt it.

As an initial matter, although the Third Circuit has never ruled on Hatch-Waxman settlements specifically, it (like all federal courts) has long recognized the value of litigation settlements and the need to encourage them. *See, e.g.*, *Wilcher v. City of Wilmington*, 139 F.3d 366, 372 (3d Cir. 1998) ("As a general rule, we encourage attempts to settle disagreements outside the litigative context."); *D.R. by M.R. v. East Brunswick Bd. of Educ.*, 109 F.3d 896, 901 (3d Cir. 1997) ("Settlement agreements are encouraged as a matter of public policy because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by courts."). This policy extends to settlements of patent litigation, including settlements for money. "Where there are legitimately conflicting claims or threatened interferences [with a patent], a settlement by agreement, rather than litigation, is not precluded by the [antitrust laws]." *Standard Oil Co. v. United States*, 283 U.S. 163, 171 (1931); *see also Cipro Fed. Cir.*, 544 F.3d at 1333 ("Settlement of patent claims by agreement between the parties—including exchange of consideration—rather than by litigation is not precluded by the Sherman Act even though it may have some adverse effects on competition."); *Tamoxifen*, 466 F.3d at 203. A rule making Hatch-Waxman patent settlements presumptively unlawful would contravene these fundamental principles.

And contrary to the positions taken by the government and the plaintiffs, *see* U.S. 2d Cir. Br. at 22; Directs Compl. ¶ 2; End Payors Compl. ¶ 2, there is nothing inherently suspect about a settlement containing a payment from the patent holder to the alleged infringer. *See, e.g.*, *Valley Drug*, 344 F.3d at 1309 ("We cannot conclude that the exclusionary effect of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the [] patent merely because [the patent holder]

paid [the generic challengers] in return for their respective agreements."). Indeed, virtually *every* patent settlement—even those outside the Hatch-Waxman context—includes some form of consideration from the patent holder to the alleged infringer. As Judge Posner observed, "*any* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement." *Asahi Glass*, 289 F. Supp. 2d at 994 (emphasis in original); *see also Schering-Plough*, 402 F.3d at 1074 ("[E]ven in the pre-Hatch-Waxman context, 'implicit consideration flows from the patent holder to the alleged infringer.'" (quoting *Cipro I*, 261 F. Supp. 2d at 251)); *Tamoxifen*, 466 F.3d at 207 n.20; *Metro-Goldwyn Mayer, Inc. v. 007 Safety Prods., Inc.*, 183 F.3d 10, 13 (1st Cir. 1999) (enforcing non-patent intellectual property settlement that included a payment to the alleged infringer).

Moreover, so-called "reverse payments are a natural by-product of the Hatch-Waxman process." *Cipro I*, 261 F. Supp. 2d at 252; *see also Schering-Plough*, 402 F.3d at 1074 (same); *Tamoxifen*, 466 F.3d at 206 ("[R]everse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them."). This is so, as the courts have explained, because Hatch-Waxman reverses the traditional risks associated with patent litigation. A generic manufacturer can challenge the patent on a branded drug by filing an ANDA containing a Paragraph IV certification without actually entering the market and risking infringement damages. *See Tamoxifen*, 466 F.3d at 206-07; *see also* 35 U.S.C. § 271(e); 21 U.S.C. § 355(j)(2)(A)(vii). As a result, even if the generic manufacturer is unsuccessful in its challenge, it has little if any monetary exposure. *See Cipro Fed. Cir.*, 544 F.3d at 1338. By contrast, a loss for the brand manufacturer would invalidate

its patent, quickly costing it potentially billions of dollars in sales. *See Tamoxifen*, 466 F.3d at 210 (describing the generic challenger as having "the whip hand"). "Given the asymmetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement." *Valley Drug*, 344 F.3d at 1310. For this reason, settlement payments in Hatch-Waxman cases naturally flow from the patent holder to the generic challenger and "a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected ...." *Cipro Fed. Cir.*, 544 F.3d at 1333 n.11; *see also Schering-Plough*, 402 F.3d at 1074 ("Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude.").

The "presumptively unlawful" standard is thus no more than a reformulation of the arguments made for years by certain academic commentators and the Federal Trade Commission that settlements of patent litigation containing monetary consideration should be banned. But "the antitrust laws do not permit courts to ban all practices that some economists consider undesirable." *Buffalo Broad. Co., Inc. v. Am. Soc'y of Composers, Authors and Publishers*, 744 F.2d 917, 933 (2d Cir. 1984). Indeed, such a blanket rule would itself be anticompetitive. As Judge Posner observed, "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass*, 289 F. Supp. 2d at 994; *cf. Valley Drug*, 344 F.3d at 1308 ("By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation."). Such restrictions could thereby discourage a variety of

pro-competitive outcomes, including settlements—such as this one—that will allow the generic challengers to sell competing products a full *three years* before the patentee's exclusivity ends.

B. Hatch-Waxman Settlements Involving Monetary Payments Are Not *Per Se* Illegal.

Plaintiffs' complaints go even further, arguing that "Defendants' agreements not to compete constitute horizontal market allocation and price-fixing agreements, which are *per se* violations of Section 1 of the Sherman Act." Directs Compl. ¶ 9; End Payors Compl. ¶ 8 (similar); *see also* Directs Compl. ¶¶ 153, 160; End Payors Compl. ¶ 153.

The problem for plaintiffs is that every federal court to consider this argument has rejected it and declined to attach either the "market allocation" or "*per se*" label to the settlements of Hatch-Waxman patent litigation. *See, e.g.*, *Cipro Fed. Cir.*, 544 F.3d at 1332 (affirming district court order rejecting the *per se* analysis); *Tamoxifen*, 466 F.3d at 212 (holding that making Hatch-Waxman settlements *per se* illegal "would be contrary to well-established principles of law" including encouraging settlement of litigation); *Valley Drug*, 344 F.3d at 1305 ("To the extent that [Defendants] agreed not to market admittedly infringing products before the [] patent expires or was held invalid, the market allocation characterization is inappropriate."); *Cipro I*, 261 F. Supp. 2d at 239-55 (same); *see also* Thomas F. Cotter, *Refining the "Presumptive Illegality" Approach to Settlements of Patent Disputes Involving Reverse Payments: A Commentary on Hovenkamp, Janis & Lemley*, 87 Minn. L. Rev. 1789, 1807 (2003) (noting that "reverse payments should not be *per se* illegal, since they are just as consistent with a high probability of validity and infringement as they are with a low probability"). Indeed, even the government acknowledges that Hatch-Waxman settlements "are not

properly characterized as naked agreements not to compete," *id.* at 20, and should not be *per se* illegal, *id.* at 19-21, because "[t]he vast majority of settlements in patent cases are likely to be efficiency enhancing and lawful," *id.* at 20.

As these courts have held, there is nothing inherently anti-competitive about a litigation settlement that would satisfy the high burden for applying the *per se* label. *See Northern Pacific Ry. Co. v. United States*, 356 U.S. 1, 5 (1958) (to be *per se* illegal, conduct must have a "pernicious effect on competition" and "lack any redeeming virtue"). There is no reason for this Court to hold otherwise.

IV. Plaintiffs Have Not Plausibly Alleged That The Generic Defendants Conspired To Restrain Trade, And Absent Such Allegations Cannot Establish Causation.

Over and above the fact that plaintiffs cannot base their antitrust claims on the allegation that the Provigil® Settlements contained so-called "reverse payments" or on allegations that the Generic Defendants "would have won" the patent cases, plaintiffs' complaints also fail because they do not allege the necessary causal link between the alleged conduct and plaintiffs' claimed injury.

Plaintiffs allege that because the Generic Defendants all filed their ANDAs on the first possible day, they shared 180 days of generic exclusivity. *See, e.g.*, Directs Compl. ¶ 51. As such, the unilateral decision of any one Generic Defendant to settle its patent case with Cephalon could not cause the injury to competition asserted by plaintiffs—the patent litigation would have continued in the other cases, and, according to plaintiffs, would have resulted in the invalidation of the RE '516 Patent and competition in the market for Provigil®. *See, e.g.*, Directs Compl. ¶ 7. It is for this reason that the Directs allege that "[i]f the Generic Defendants had not *collectively*

agreed to stay off the market until April 2012 at least one, if not all of them would have entered the market no later than 2006." Directs Compl. ¶ 191 (emphasis added). And if any one Generic Defendant had not settled, then plaintiffs contend that "Plaintiffs and other Class members would have substituted lower-priced generic modafinil for the higher-priced brand name Provigil ... and/or would have received lower prices on some or all of their remaining Provigil purchases." *Id.*

Thus, according to plaintiffs' own allegations, the only injury to competition stemmed from a settlement *of all four* patent cases, not the settlement of any one case. Because no one Generic Defendant alone could have caused the alleged harm, plaintiffs must further allege that the Generic Defendants conspired together to end their respective challenges in order to prevent such competition. Allegations that a Generic Defendant decided unilaterally to end its patent challenge are not sufficient, because any decision by one generic company—standing alone—would have ended only that generic's patent challenge. Plaintiffs' complaints are therefore based on the premise that the Generic Defendants made a joint decision to settle all of the patent cases in order to preclude competition in the Provigil® market. *See* Directs Compl. ¶ 107 ("each Generic Defendants' agreement was not an isolated deal but part of a larger agreement to restrain trade"); *id.* ¶ 191 (alleging that the Generic Defendants "collectively agreed to stay off the market until April 2012"); *see also id.* ¶¶ 7, 186-92.

This conspiracy claim fails, however, because plaintiffs' complaints are completely devoid of the factual allegations necessary to make this claim plausible. *See Twombly*, 550 U.S. at 556-57. As an initial matter, plaintiffs have not even alleged the core of a conspiracy claim—that the Generic Defendants *communicated* with one

another prior to or during their respective settlement negotiations with Cephalon. A search of the complaints will reveal no allegation of *any* communication between any two Generic Defendants concerning the Provigil® Settlements. Plaintiffs do not allege any facts regarding how the Generic Defendants could have achieved a "meeting of the minds" on a joint agreement to prevent competition in the market for Provigil® without ever discussing the idea. *See Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (affirming an order dismissing under Rule 12(b)(6) an antitrust claim alleging a conspiracy to restrain trade because plaintiff "did not allege any meetings ..., any communications ..., or any other means by which [the] alleged conspiracy came about").

Plaintiffs' allegations are instead limited to statements that the Generic Defendants "became aware of" the agreements with the other Generic Defendants, Directs Compl. ¶ 107, and assertions that it would make no sense for some, but not all, of the Generic Defendants to enter into a settlement agreement because that could result in the non-settling Generic Defendants coming to market before the Generic Defendants that settled, *id.* ¶ 106. But these are precisely the type of conclusory allegations the Supreme Court found inadequate to state a Sherman Act claim in *Twombly*. "[A]n allegation of parallel conduct and a bare assertion of conspiracy will not suffice. Without more, parallel conduct does not suggest conspiracy, and a conclusory allegation of agreement at some unidentified point does not supply facts adequate to show illegality." 550 U.S. at 556-57. Because plaintiffs' allegations are "not only compatible with, but indeed [] more likely explained by, lawful, unchoreographed free-market behavior," they have failed to state a claim of conspiracy

to restrain trade among the Generic Defendants. *See Iqbal*, 129 S. Ct. at 1950 (citing *Twombly*, 550 U.S. at 567). Indeed, plaintiffs' complaints affirmatively allege that the Generic Defendants each had its own independent business reasons to settle, namely the monetary consideration provided by Cephalon.[8] *See, e.g.*, Directs Compl. ¶ 123 ("The compensation Cephalon agreed to provide Mylan was designed to, and did, induce Mylan to settle...."); *id.* ¶¶ 111, 117-18, 125 (similar).

Plaintiffs' conclusory claim of conspiracy is also belied by other specific allegations in plaintiffs' complaints. For example, plaintiffs allege that the Provigil® Settlements each contained a provision that would allow the generic company to come to market as soon as *any* company began marketing a generic Provigil® product. *See* Directs Compl. ¶ 87; End Payors Compl. ¶ 99. Plaintiffs do not explain why a settling Generic Defendant would be concerned with protecting itself with such a provision in the event that another Generic Defendant launched, if the Generic Defendants were acting in concert. Further, plaintiffs allege not only that the Generic Defendants settled "seriatim" on different dates over a six-week period, but also that they received radically different consideration from Cephalon. *See* Directs Compl. ¶¶ 106, 108-30. Such differing consideration is, itself, far more consistent with "unchoreographed free market behavior" than plaintiffs' alleged conspiracy. *See Iqbal*, 129 S. Ct. at 1950 (citing *Twombly*, 550 U.S. at 556-57). All of the above contradictions are fatal to plaintiffs' claim. *See, e.g.*, *Delaware Nation v. Pennsylvania*, 446 F.3d 410, 417 (3d Cir.

[8] The Generic Defendants strongly contest plaintiffs' characterizations of the nature and purpose of payments received from Cephalon, but accept them solely for purposes of this motion.

2006) (affirming the dismissal of claim where plaintiffs posited contradictory allegations in the complaint).

At the end of the day, plaintiffs have no plausible claim that the Generic Defendants acted in concert to harm competition. And absent a claim of concerted behavior, plaintiffs cannot show the necessary causal link between the Generic Defendants' individual settlement agreements and the alleged injury—a restriction on competition in the market for Provigil®. Plaintiffs' Sherman Act claims thus fail as a matter of law.

V. The End Payor Plaintiffs' Complaint Should Be Dismissed For Additional Reasons.

In addition to failing to state a valid claim under the antitrust laws, the End Payors' Complaint must be dismissed because (1) the End Payors lack standing to raise an antitrust claim under *Associated General Contractors of California, Inc. v. California State Council of Carpenters* ("*Associated General*"), 459 U.S. 519 (1983), and its progeny; (2) Count V fails to state a cause of action in equity for unjust enrichment against the Generic Defendants.[9]

A. The Third Party Payors Do Not Have Standing.

As an initial matter, the End Payor plaintiffs that are actually so-called "Third Party Payors," *i.e.* not consumers but entities that reimburse consumers, do not have standing to raise antitrust claims under *Associated General*, 459 U.S. 519, 532 n.25 (1983). These Third Party Payors (including Vista Healthplan, Inc., The Pennsylvania Employees Benefit Trust Fund, the Pennsylvania Turnpike Commission, the District

[9] The Generic Defendants also join in the arguments raised by Cephalon regarding the state law claims in its motions to dismiss the complaints of the End Payor Plaintiffs and Avmed.

Council 37 Health & Security Plan, and Avmed) are entities that provide or administer health benefits for individual consumers. *See* End Payors Compl. ¶¶ 13-14, 16-17; Avmed Compl. ¶ 16.

The Third Party Payors do not purchase Provigil® directly from Cephalon, nor do they claim to have bought it from Cephalon's customers. Instead, these Third Party Payors allege only that they covered a portion of the costs of Provigil® dispensed to end-paying consumers. In others words, the Third Party Payors allege only that they suffered harm from having to pay higher reimbursements *after* Cephalon sold Provigil® to direct purchasers; *after* those direct purchasers, in turn, sold Provigil® to their customers; *after* consumers went to their doctors and obtained prescriptions for Provigil®; *after* consumers went to a drug store to fill their prescription; and *after* those consumers sought reimbursement from the Third Party Payors.

The Third Party Payors plainly do not have standing. In *Associated General*, the Supreme Court outlined the factors that courts must consider when determining whether a party has "antitrust standing," *i.e.*, whether plaintiffs may bring an antitrust action for their alleged harms. *See* 459 U.S. at 535 n.31. Antitrust standing is distinct from constitutional standing; even if the party satisfies Article III, "the court must make a further determination whether the plaintiff is a proper party to bring an antitrust action." *Id.*; *see also City of Pittsburgh v. West Penn Power Co.*, 147 F.3d 256, 264 (3d Cir. 1998). "[A] plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts [is] generally said to stand at too remote a distance to recover." *Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268-69 (1992).

The factors outlined by the Court include:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause that harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

West Penn, 147 F.3d at 264; *see also Associated General*, 459 U.S. at 536-45. According to the Third Circuit, "[t]he *Associated General* test has been regularly and consistently applied as the *passageway though which antitrust plaintiffs must advance*...." *West Penn*, 147 F.3d at 264 (emphasis added). The Third Party Plaintiffs cannot satisfy these requirements.

First, the complaints allege, at most, a remote, indirect causal connection between the alleged antitrust violation and the alleged harm to plaintiffs, and contain absolutely no allegations of intent. The Third Party Payors' claims are fully contingent on alleged harm to others. The Third Party Payors do not allege that they purchased Provigil® directly from Cephalon or directly from Cephalon's customers. Nor have they alleged facts to show that they would have suffered the same injuries independent of the harm allegedly sustained by individual consumers, wholesalers, and/or pharmacies. At best, the Third Party Payors can allege that they suffered harm *after* some consumers sought to have their health benefit plans cover Provigil® prescriptions—and it is undisputed that, without those intermediary steps, no reimbursements would have been made at all. The Third Party Payors likewise do not and cannot allege that

Defendants *intended* to harm them, given that even under the allegedly unlawful "scheme," Defendants could have continued selling Provigil® to wholesalers, pharmacies and individual consumers, with or without the presence of the Third Party Payors. At bottom, the Third Party Payors simply piggy-back on the alleged injuries of more direct purchasers of Provigil®, which is insufficient to state an antitrust claim. *See Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d 912, 927-28 (3d Cir. 1999).

Second, the injuries allegedly suffered by the Third Party Payors are too remote to give rise to an antitrust claim. As described above, the Third Party Payors paid, in part, for their clients' Provigil® purchases through several layers of commerce. In order to prove their claims, then, they would have to show that at each step in the supply chain, each previous purchaser bought and sold Provigil® at the alleged supra-competitive price, and that at no point along the way did a purchaser charge a lower price in order to compete with other sellers of Provigil®. In short, it will be nearly impossible for Third Party Payors to establish that they paid prices that were not independent of the prices charged by Cephalon. Absent this showing, the Third Party Payors cannot establish that they were harmed by Cephalon (much less the Generic Defendants), which is necessary to establish standing. *See Kansas v. UtiliCorp United, Inc.*, 497 U.S. 199, 213 (1990) (dismissing antitrust complaint due to the complexity of proving actual injury by indirect purchasers); *see also West Penn*, 147 F.3d at 265.

Third, the fact that a purported class of entities that purchased Provigil® directly from Cephalon (the Direct Purchasers) are also challenging the Provigil® Settlements counsels against allowing indirect purchasers such as the Third Party

Payors to proceed. As the Supreme Court held in *Associated General*, "[t]he existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement diminishes the justification for allowing a more remote party such as the [plaintiff] to perform the office of a private attorney general." 459 U.S. at 542; *2660 Woodley Rd. Joint Venture v. ITT Sheraton Corp.*, 369 F.3d 732, 741-42 (3d Cir. 2004). The Third Circuit has held that permitting direct and indirect purchasers to sue over the same alleged conduct could result in the inefficient enforcement of the antitrust laws and should be avoided. *Howard Hess Dental Labs. Inc. v. Dentsply Int'l, Inc.*, 424 F.3d 363, 369-70 (3d Cir. 2005).

Fourth, and related, the Third Party Payors' claims are inappropriate because any damages awarded to them would be duplicative of those awarded to more direct plaintiffs who have already asserted claims on their own behalf. The Third Circuit has denied standing where, as here, the recognition of remote and attenuated claims would require such complex damages inquiries and risk saddling defendants with duplicative damage awards. *See, e.g., Conte Bros. Auto Inc. v. Quaker State-Slick 50, Inc.*, 165 F.3d 221, 235 (3d Cir. 1988) ("[R]ecognizing the right of every potentially injured party in the distribution chain to bring a private damages action would subject defendant firms to multiple liability for the same conduct and would result in administratively complex damages proceedings."); *see also Steamfitters*, 171 F.3d at 930. The Third Party Payors thus lack standing under *Associated General* and their claims should be dismissed.

B. The Unjust Enrichment Claims Are Defective As A Matter Of Law.

The End Payor Plaintiffs' claim for unjust enrichment also fails. A cause of action for unjust enrichment generally requires that (1) the plaintiff conferred a benefit

on the defendant; (2) the defendant knew about the benefit; (3) the defendant accepted or retained the benefit; and (4) it would be inequitable for the defendant to retain the benefit without paying fair value for it. *Commerce P'ship 8098 Ltd. v. Equity Contracting Co.*, 695 So. 2d 383, 386 (Fla. Dist. Ct. App. 1997); *accord Clifford R. Gray, Inc. v. LeChase Constr. Serv., LLC*, 31 A.D.3d 983, 98-88 (N.Y. App. Div., 3d Dept. 2006). Plaintiff's unjust enrichment claim fails.[10]

First, plaintiffs did not confer on the Generic Defendants a benefit that would support an unjust enrichment claim. As an initial matter, plaintiffs do not and cannot allege that they provided any direct or indirect benefit to the Generic Defendants when they purchased Provigil®. After all, the Generic Defendants do not sell Provigil® (only Cephalon does), meaning they could not have sold it to plaintiffs at any price, inflated or otherwise. And although plaintiffs claim that "the Generic Defendants have been unjustly enriched ... by the receipt of any and all payments made to them by Cephalon," *see* End Payors Compl. ¶ 182, plaintiffs do not even attempt to explain how this is a benefit conferred *by plaintiffs*. As plaintiffs' complaint contains no other allegations regarding supposed unjust enrichment from plaintiffs to the Generic Defendants, the claim fails as a matter of law. *See Clifford Gray*, 31 A.D.3d at 987-88.

Second, under the law of New York—the state of residence of the only consumer End Payor Plaintiff (as well as District Council 37 Health & Security Plan)—an unjust enrichment claim cannot be asserted against a defendant where the relationship

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[10] Oddly, plaintiffs do not allege under what state's law they seek unjust enrichment. The named plaintiffs are residents of Florida, New York and Pennsylvania. Because antitrust claims for monetary damages are barred under Pennsylvania law, *see XF Enters. Inc. v. BASF Corp.*, 47 Pa. D. & C. 4th 147, 150-51 (Pa. Comm. Pl. 2000); *InterVest, Inc. v. Bloomberg, L.P.*, 340 F.3d 144, 158 (3d Cir. 2003), the analysis focuses on the law of Florida and New York.

between the plaintiff and defendant is too attenuated. *See Sperry v. Crompton Corp.*, 8 N.Y.3d 204, 215-216 (N.Y. 2007). The plaintiffs do not allege that they bought Provigil® from the Generic Defendants, because the Generic Defendants do not sell Provigil®. Moreover, the Third Party Payors and consumers are not in privity with the Generic Defendants—they are in privity either with each other or with an entity that purchased Provigil® from a customer of Cephalon. The tenuous connection between plaintiffs and Generic Defendants is fatal to plaintiffs' unjust enrichment claim.

Third, under Florida law, where one other End Payor Plaintiff allegedly resides, a plaintiff asserting an unjust enrichment claim must show that it has exhausted its remedies against that party prior to bringing suit. *See Maloney v. Therm Alum Indus., Corp.*, 636 So. 2d 767, 770 (Fla. Dist. Ct. App. 1994) ("[A] material element that must be alleged and proved for a claim of unjust enrichment [against a remote defendant] to succeed is that the remedies against [the party with whom the plaintiff is in privity] were exhausted."), *overruled in part on other grounds by Commerce P'ship*, 695 So.2d at 387-89. Once again, plaintiffs have not made such an allegation.

Finally, the End Payor Plaintiffs do not deny that they voluntarily entered into valid commercial transactions to purchase Provigil®, nor do they allege that they entered into those valid commercial transactions by fraud, accident, or mistake of fact. An unjust enrichment claim cannot be used to attack a contract that the plaintiffs do not contend was invalid or entered into by fraud, accident or mistake of fact. *See In re Microsoft Antitrust Litig.*, 401 F. Supp. 2d 461, 464-65 (D. Md. 2005) (finding where plaintiff has entered into valid commercial transactions, plaintiff cannot recover under a theory of unjust enrichment).

VI. Plaintiffs Should Not Be Permitted To Further Amend The Complaints.

Plaintiffs should not be permitted to amend their complaints yet again. The Third Circuit has held that a district court acts well within its discretion to deny leave to amend a complaint if doing so would be "futile" or if it is not required in the interests of justice. *Lake v. Arnold*, 232 F.3d 360, 373 (3d Cir. 2000). District courts are afforded "even broader discretion when, as here, the court has already granted the requesting party an opportunity to amend its complaint." *Id.* at 374.

Plaintiffs have already had an opportunity to re-plead this case, after viewing all of Defendants' motion to dismiss arguments and in light of the many federal cases that have adjudicated this precise issue. Put simply, plaintiffs knew what the legal standard was and made the best possible allegations they could make. There is nothing they can do to "cure" their complaints to make them state a claim. *See St. Clair v. Citizens Fin. Group*, No. 08-4870, 2009 WL 2186515, at *4 (3d Cir. July 23, 2009) (affirming district court's order denying leave to amend complaint a second time when plaintiff had "filed 123 pages of pleadings, a case statement, and a brief in opposition to the motion to dismiss").

CONCLUSION

For the foregoing reasons, Generic Defendants respectfully request that the Court grant the motion to dismiss.

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CERTIFICATE OF SERVICE

The undersigned certifies that on the 31st day of August 2009 he caused to be filed electronically the foregoing Motion to Dismiss the Amended Complaints of the Direct Purchaser Plaintiffs and End Payor Plaintiffs, the Memorandum in Support, and the Proposed Order, using the CM/ECF system, which will send e-mail notification of the filing to all counsel of record.

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